In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: August 2, 2019

BREEANN MILLER, *on behalf of A.M., a minor,*	*	Unpublished
Petitioner,	*	No. 18-587V
v.	*	Special Master Gowen
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Acute Encephalopathy; Ruling on Entitlement
Respondent.	*	

Mark T. Sadaka, Mark T. Sadaka, LLC, Englewood, NJ, for petitioner.
Ashley M. Simpson, Department of Justice, Washington, D.C., for respondent.

RULING ON ENTITLEMENT[1]

On April 25, 2018, Breeann Miller, on behalf of A.M., a minor ("petitioner"), filed a petition for compensation pursuant to the National Vaccine Injury Compensation Program.[2] Petition at ¶ 1 (ECF No. 1). Petitioner alleges the measles, mumps, rubella and varicella (MMR+V) A.M. received on May 27, 2015 and the diphtheria, tetanus, and pertussis ("DTAP") she received on May 29, 2015 caused A.M. to suffer vaccine-induced seizures and encephalopathy. Petition at Preamble. Petitioner alleges that A.M. meets the criteria for Table Encephalopathy, as codified at 42 U.S.C. §300aa-14 ("Vaccine Injury Table"). Petitioner's Memorandum in Support of Table Claim Injury ("Pet. Memo").

[1] Pursuant to the E-Government Act of 2002, *see* 44 U.S.C. § 3501 note (2012), because this decision contains a reasoned explanation for the action in this case, I am required to post it on the website of the United States Court of Federal Claims. The court's website is at http://www.uscfc.uscourts.gov/aggregator/sources/7. **This means the Ruling will be available to anyone with access to the Internet.** Before the decision is posted on the court's website, each party has 14 days to file a motion requesting redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). "An objecting party must provide the court with a proposed redacted version of the decision." *Id.* **If neither party files a motion for redaction within 14 days, the decision will be posted on the court's website without any changes.** *Id.*

[2] The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 *et seq.* (hereinafter "Vaccine Act" or "the Act"). Hereafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

After a fact hearing held on May 17, 2019 and reviewing the record as a whole, I found that A.M. met the criteria for Table Encephalopathy.[3] I issued a ruling from the bench and this decision provides further explanation for that ruling.

I. Procedural History

In support of her petition, petitioner filed medical records on May 2, 2018 (ECF No. 5). Petitioner filed an affidavit on June 6, 2018 and a statement of completion on June 18, 2018.

On October 1, 2018, respondent filed his report pursuant to Vaccine Rule 4(c). contesting Petitioner's claim. (ECF No. 11). Specifically, respondent argues that petitioner cannot make a table encephalopathy claim because the medical records do not establish that A.M. suffered an encephalopathy. Respondent's Report ("Resp. Rep.") at 11. Respondent's report continues to discuss a Table encephalopathy claim as it relates to a child under the age of 18-months old and younger. *Id.* The argument presented in the report is mostly irrelevant as A.M. was older than 18-months old when she received the MMRV vaccination on May 27, 2015.

On November 20, 2018, I held a status conference where I directed petitioner to review the medical records and show a decreased level of consciousness in A.M. over a 24-hour period as well as a memo supporting petitioner's claim for a Table encephalopathy injury within the bounds of the Qualifications and Aids to Interpretation ("QAI"). *See* Order (ECF No. 12). Petitioner filed the supporting memo on December 21, 2018. (ECF No. 15). Respondent filed a status report on February 19, 2019 disagreeing with petitioner's interpretation of A.M.'s medical record and again arguing that A.M. did not meet the QAI requirements for a Table injury. (ECF No. 19).

On March 26, 2019, I held another status conference to review the parties' memos. *See* Order (ECF No. 20). During the status conference, I stated that the respondent should focus on whether A.M. suffered an acute encephalopathy provided at 42 C.F.R. §100.3(c)(2)(i)(B), which is the Table definition for acute encephalopathy for adults and children 18-months of age or older. At the end of the status conference, A.M.'s state of consciousness in the ten days following vaccination had yet to be resolved and fact hearing was set to elicit additional testimony regarding petitioner's level of consciousness during the relevant period at issue. Order at 4 (ECF No. 20).

The fact hearing was held in Santa Fe, New Mexico on May 17, 2019. Petitioner Breeann Miller, Elisha Miller, and Randy Barboa testified on behalf of A.M. (ECF No. 25).

II. Legal Standard

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records, which are required to be filed with the petition. §11(c)(2). The Federal Circuit has made clear that medical records "warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528. Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete"

[3] 42 C.F.R. §100.3(c)(2).

(i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528.

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19.

The Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (*citing Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

A special master's ruling on entitlement may be delivered from the bench, with no written opinion. *Doe/17 v. Sec'y of Health & Human Servs.,* 84 Fed. Cl. 691, 704 n.18 (2008). A published written decision memorializing a decision from the bench allows the public access to the reasoning underlying the bench decision. *See Heddens v. Sec'y of Health & Human Servs.*, No. 15-734, 2018 WL 5726991 (Fed. Cl. Spec. Mstr. Oct. 5, 2018); *Jaafar, on behalf of A.M. v. Sec'y of Health & Human Servs.,* No. 15-267, 2018 WL 4519066 (Fed. Cl. Spec. Mstr. Aug. 10, 2018). Further, issuing a written decision provides an abbreviated recitation for the basis of decision. *See Hebern v. U.S.*, 54 Fed. Cl. 548 (2002) (example of order affirming bench ruling).

This particular written decision is consistent with, but more fully explains the earlier bench ruling.

III. Requirements for a Table Encephalopathy

In order to establish a Table Injury claim for entitlement resulting from the MMRV vaccination, a petitioner must show that the encephalopathy has manifested five to fifteen days after vaccine administration. 42 C.F.R. §100.3. It must be shown that acute encephalopathy is followed by the persistence of chronic encephalopathy for more than six months beyond the date of vaccination. *Id.*

"For children 18 months or older and adults an acute encephalopathy is one that persists at least 24 hours and is characterized by at least two of the following: 1) a significant change in mental status that is not medication related (such as a confusional state, delirium, or psychosis); 2) a significantly decreased level of consciousness which is independent of a seizure and cannot be attributed to the effects of medication; and 3) a seizure associated with the loss of consciousness." 42 C.F.R. § 100.3(c)(2)(i)(B).

"A significantly decreased level of consciousness is indicated by the presence of one or more of the following clinical signs: (i) decreased or absent response to environment; (ii) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or (iii) inconsistent or absent responses to external stimuli (does not recognize familiar people or things)." § 100.3(d)(4)(i)-(iii). "Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying and bulging fontanelle are insufficient, standing alone or in combination, to determine an acute encephalopathy." §100.3(c)(2)(i)(C).

A chronic encephalopathy is defined in the QAI as "a change in mental or neurologic status, first manifested during the applicable Table time period as an acute encephalopathy, persists for at least 6 months from the first symptom or manifestation of onset…" §100.3(c)(1). Individuals who return to their baseline neurologic state, as confirmed by clinical findings, within less than six months from the first symptom or manifestation of onset…of acute encephalopathy…shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be the sequela of the acute encephalopathy. §100.3(d)(1)(i)-(ii).

The QAI definition of significantly decreased level of consciousness "implies a state of diminished alertness that is much more than mere sleepiness or inattentiveness….[it] requires markedly impaired or strikingly absent-responsiveness to environmental or external stimuli for a sustained period of at least 24-hours." *Wright v. Sec'y of Health & Human Servs,* No. 12-423, 2015 WL 6665600 at *6 (Fed. Cl. Spec. Mstr. Sept. 21, 2015) (quoting *Waddell v. Sec'y of Health & Human Servs.*, No. 10-316, 2012 WL 4829291 at *7 (Fed. Cl. Spec. Mstr. Sept. 19, 2012)).

III. Relevant Medical Records

A.M. was a healthy baby born on November 19, 2013. Petitioner's Exhibit ("Pet. Ex.") 1 at 336. On May 27, 2015, at her 18-month well-child appointment, A.M. received her Measles, Mumps, Rubella and Varicella ("MMRV") vaccination. Pet. Ex. 3 at 211. A.M. was well appearing and her parents reported no complaints or concerns. *Id.* at 211-12. Two days later, A.M. received her Haemophilus Influenzae ("HIB") #3 and Diphtheria, Tetanus, Pertussis ("DTaP") vaccinations. *Id.* at 319.

In the evening of June 3, 2015, A.M.'s parents witnessed her having a seizure which they described as, her just dropping to the floor and turned blue. Tr. 15. They called 911 and the ambulance arrived at the Miller's home approximately ten minutes after dispatch. Pet. Ex. 1 at 295. The emergency responders observed A.M. as "awake but postictal" with a temperature of 99.9 degrees Fahrenheit. Pet. Ex. 1 at 296. Emergency services transported A.M. to the San Juan Regional Medical Center. Pet. Ex. 1 at 295. At the emergency room, Dr. Kennard Stradling observed A.M. as agitated and described her movement as "non-purposeful." *Id.* at 283. In the history, he noted that the seizure was "sudden" and quality was described as "tonic clonic." *Id.* at 284. Additionally, A.M.'s parents reported a fever earlier that evening, prior to the seizure. *Id.* Dr. Stradling diagnosed A.M. with febrile seizure and viral syndrome and she was discharged to home at 9:31 pm. *Id.* at 293.

The following day, June 4, 2015, after becoming increasingly worried about A.M.'s behavior, at the recommendation of their pediatrician's nurse, Ms. Miller transported A.M. back to San Juan Regional Medical Center. Pet. Aff.at ¶ 9. Ms. Miller reported that A.M. was not making eye contact, was not eating or drinking, did not urinate, was gazing off and was lethargic in nature. Pet. Ex. 1 at 211. Upon arrival at the emergency room, A.M.'s vitals were taken and she had a low-grade fever of 99.2 degrees Fahrenheit. *Id.* As A.M. was in the process of being discharged from the emergency room, she had a seizure that lasted approximately for one minute where her eyes rolled back in her head and she turned blue. The nurse present bagged her until oxygen saturations returned to normal and Ativan was administered intravenously. *Id.* at 205, 220-221. At that point, A.M. was admitted to the pediatric floor for observation with the diagnosis of complex febrile seizure. *Id.* at 205, 221.

While in the hospital, A.M. continued to experience low-grade temperatures, but had no further seizure activity. *Id.* The attending physician, Dr. William Barkman stated that through the hospital course:

> She [A.M.] remained somewhat lethargic and even obtunded at times. She had stable vital signs. Over the following 36 hours, the child became more alert, playful, began eating and drinking and had no further fever. She had no further seizure activity.

Pet. Ex. 1 at 205.

Petitioner was discharged on June 6, 2015. *Id.* at 205. On the discharge summary, Dr. Barkman stated, "Of note is the fact that the patient had recently undergone her 18-month

vaccinations, including MMRV #1 occurring about 5 days prior to admission and DTaP #3 given approximately seven days prior to admission."[4] *Id.*

On June 17, 2015, A.M. saw her primary care physician, Dr. Ronald Bliss for a follow-up of her recent seizures and hospitalization. Pet. Ex. 3 at 206. A.M.'s physical exam was normal and her temperature was recorded as normal. *Id.* at 207. Dr. Bliss recommended that A.M. delay further vaccinations until five-years old, reasoning, "I suspect her seizures were related to the MMR immunizations." *Id.*

Following the first two seizures in June 2015, A.M. continued to experience seizures. *See* Pet. Ex. 1 at 20-22, 70-71; Pet. Ex. 3 at 194, 200-01; & Pet. Ex. 11 at 4-6. In September 2015, A.M. saw Dr. Bliss for balance issues, a decline in her cognitive abilities and staring off into space. Pet. Ex. 3 at 200-01. Dr. Bliss diagnosed A.M. with typical febrile seizures following immunizations, developmental delays and speech delay. *Id.* In early January 2016, A.M. experienced two other seizure episodes. Pet. Ex. 1 at 147. While the family was eating out, A.M. suddenly sat-back, her eyes rolled to the back of her head and she was unresponsive. *Id.* After the event, her balance was off and she was falling to the ground for no reason. *Id.* A few hours later, A.M.'s eyes rolled to the back of her head, she was unresponsive and there was shaking in her right arm. *Id.* A.M. was taken to her family pediatrician who assessed A.M. with juvenile absence seizures. *Id.* at 148.

On January 15, 2016, A.M. was seen by Dr. Letellier, a naturopathic doctor. Pet. Ex. 11 at 39. She assessed A.M. with developmental delays, including an inability to jump, kick a ball, name one color and combine words. *Id.*

On July 23, 2016, A.M. suffered another seizure where she nearly drowned during a bath. Pet. Ex. 11 at 4. Throughout the day, A.M. did not eat lunch and had diarrhea. *Id.* at 31. A.M. had a temperature of 101 degrees Fahrenheit. *Id.* Ms. Miller went to retrieve a towel and found A.M. facedown in the water and was blue. Pet. Ex. 9 at 1. A.M. was hospitalized overnight for observation. Pet. Ex. 11 at 4. Then in mid-February 2017, A.M. suffered another seizure while in daycare. Pet. Ex. 9 at 1; Pet. Ex. 3 at 59. She experienced another seizure later that night. Pet. Ex. 3 at 59. Dr. Bliss diagnosed A.M. with a "seizure disorder, epilepsy, unspecified, not intractable." *Id.*

On May 19, 2017, A.M. was seen by Dr. Stephen Kinsman, a pediatric neurologist. Pet. Ex. 10 at 7. He observed that A.M. has poor muscle tone. *Id.* at 9. He also assessed her with "complicated febrile convulsions" and "recurrent falls." *Id.* at 10.

IV. Summary of Parties' Arguments

The primary dispute between the parties is whether A.M. had a significantly decreased level of consciousness independent of a seizure that cannot be attributed to the effects of medication that lasted for at least 24-hours.

[4] A.M. actually received the MMRV vaccination on May 27, 2015 and the DTaP vaccination on May 29, 2015. Pet. Ex.

Petitioner argues that A.M. met the Table definition of acute encephalopathy at least twice during the period of June 3, 2015 through June 6, 2015. Petitioner states that after A.M.'s first seizure on June 3, 2015, she experienced a significantly decreased level of consciousness on June 4, 2015 that persisted until her second seizure later that evening. Pet. Memo at 6. Additionally, petitioner argues that the notation by Dr. Barkman describing A.M.'s behavior in the hospital as "somewhat lethargic and even obtunded at times," demonstrates that A.M. had a decreased level of consciousness. Further, the notation stating, "Over the following 36 hours, the child became alert, playful and began eating and drinking…" demonstrates that A.M. sustained a prolonged decreased level of consciousness during her hospital stay and it was not until after 36-hours did A.M. become more alert. *Id.* at 7.

Respondent disagrees with petitioner's interpretation of the medical records. Status Report at 1 (ECF No. 19). Respondent first argues that Dr. Barkman's description about A.M.'s behavior during her hospital stay could be attributed to a symptom of her postictal state. *Id.* at 2. Respondent then argues the description of her symptoms in the 36 hours after seizure were intermittent and not persistent in nature. *Id.* Respondent states that the use of "somewhat" and "at times" suggests that A.M. was not fully lethargic and, at times, not obtunded. *Id.* Therefore, she did not experience a sustained decreased level of consciousness for a 24-hour period.

V. Testimony of Ms. Miller, Mr. Miller and Mr. Barboa

Ms. Miller testified that on the evening of June 3, 2015, A.M. and her brother were running around, singing and dancing while she was making dinner in the kitchen. Tr. 15. The children were running in and out of the kitchen. *Id.* Then, at one point, A.M. ran in and "just dropped." *Id.* A.M.'s eyes rolled back in her head, she was making a gurgling noise and started foaming at the mouth. *Id.* A.M. convulsed for about two minutes. Tr. 16. A.M. went limp, her eyes were not moving, and she was nonverbal in her father's arms. *Id.* Mr. Miller testified that A.M. was unconscious at this point. Tr. 89

During the ride to the hospital, Ms. Miller described A.M. as being pale, limp and lifeless. Tr. 18. A.M. was not talking, her eyes were open, but she "was not there." *Id.* Ms. Miller explained that during the ride she kept touching A.M.'s hand and talking to her. *Id.* When they arrived at the hospital, A.M. was saying one or two words, but still not speaking a lot and appeared very tired. Tr. 19.

The next morning A.M. woke up between 7:30 and 8:00 AM. Tr. 20. Ms. Miller testified that A.M. did not express any interest in eating breakfast. *Id.* Normally, A.M. would want to climb into her highchair and eat, but that morning she was "stiff-legged" and did not want to be in the highchair. Tr. 21. Ms. Miller observed that A.M. was not eating or drinking and did not produce a wet diaper. *Id.* A.M. was "gazing off." *Id.* Mr. Miller testified that Ms. Miller called him while at work, expressing concern that A.M. was not "responding" and "won't look [Ms. Miller] in the eye." Tr. 93. He suggested that Ms. Miller try to give her a lollipop to coax A.M. into eating something. *Id.*

Ms. Miller attempted to entice A.M. with the lollipop, but she had a hard time grabbing for it and putting it in her mouth. *Id.* at 22. Getting increasingly concerned, Ms. Miller called

the pediatrician's office. Tr. 22. Ms. Miller told the nurse that A.M. was "not tracking anything with her eyes….or responding to me." Tr. 23. The nurse recommended that Ms. Miller take A.M. back to San Juan Regional Hospital. *Id.*

When A.M. and her mother arrived at the emergency room, they were placed into a triage room. *Id.* at 24. Ms. Miller testified that Dr. Graham Tull saw A.M. and assessed her with a "little kid funk," and that A.M. would "get over it." *Id.* While Dr. Tull left to prepare the discharge documents, A.M. experienced her second tonic-clonic seizure, immediately turning blue. *Id.* at 25. Ms. Miller explained that after the seizure, A.M. was admitted to the hospital, but it took between 9-12 hours to transfer A.M. to a room on the pediatric floor. *Id.* at 26. The medical records show that A.M.'s care was transferred to the pediatric floor on June 5, 2015 at 4:12 AM. Pet. Ex. 1 at 260.

Ms. Miller testified that immediately after the seizure in the emergency room, A.M. was "not verbal, not nodding her head, not pointing." Tr. 27. She stated that A.M. would come in and out, briefly open her eyes, but not for any significant period of time. *Id.* When they were transferred to the pediatric floor, A.M. remained asleep. *Id.* at 30. Once transferred to the pediatric floor, nurses would periodically administer Tylenol or ibuprofen to A.M. while she remained in her crib. *Id.* at 30-31. A.M. would wake up and take the medicine "without putting up any kind of wiggle or fight," and that she was "just very lifeless." *Id.* at 31.

The following day, on June 5, 2015, when A.M. woke up she was "kind of more aware of where she was," but still not herself. Tr. 32-71. That morning A.M. ate a little bit of her breakfast but did not want to walk. Tr. 31. During the day, A.M. would "stare-off." Tr. 34. Ms. Miller explained that A.M. was not playing with toys or walking and was "sleeping a lot." Tr. 67. Ms. Miller testified that A.M. stayed in bed or in her arms most of the day. *Id.*

When Ms. Miller was asked if A.M. was responsive to her, Ms. Miller explained that A.M. was more nonresponsive than responsive. *Id.* She testified that normally A.M. was very verbal. A.M. was able to speak four to five-word sentences at her 18-month wellness visit. Tr. 35. However, on June 5th, while in the hospital, Ms. Miller testified that she did not remember A.M. "speaking one word or asking anything." Tr. 69.

Later that day, A.M. was visited by her former babysitter, Stephanie Rousette. Tr. 36-37. Ms. Miller testified that A.M. did not interact with Stephanie when she came in the room. Tr. 72. When offered a stuffed animal from Ms. Rousette, A.M. did not take it. *Id.*

Mr. Miller explained that he arrived at the hospital on June 5, 2015 sometime after work. Tr. 102. He observed that A.M. was not talking, singing or playing. Tr. 104. He attempted to interact with A.M. by being "goofy" with a stuffed animal. *Id.* He said that she did not look at him. *Id.* He described A.M. as "lethargic and listless." Tr. 105.

That evening, Mr. Randy Barboa and Ms. Traci Barboa visited with the Millers at the hospital. Tr. 38, 71. A.M. did not interact with the Barboa's when they came into the room. Tr. 38. Ms. Miller testified that A.M. would normally hug them or engage with them because Traci had been A.M.'s caretaker when she was an infant. Tr. 38. Mr. Miller testified that Mr. Barboa

was a good family friend and that A.M. had a good relationship with him. Tr. 105. However, that evening, A.M. did not react to Mr. Barboa's attempts to interact with her. *Id.*

Mr. Randy Barboa testified that when he attempted to engage with A.M. in the hospital, she was "really dazed out." Tr. 77. He explained that prior to A.M.'s seizures, she would smile, walk towards him, want to hug or hold his hand. *Id.* at 78. Mr. Barboa stated that when he saw A.M. in the hospital, he said "hi" to A.M. and smiled, but she didn't respond. *Id* at 77. He said, "It wasn't the typical little girl that you knew." *Id.*

Ms. Miller testified that the morning of June 6, 2015, A.M. seemed more of her normal self. Tr. 40. A.M. was still not speaking sentences or asking questions as she normally would do, but she "wanted out of the crib." *Id.* Ms. Miller explained that A.M. wanted to open the door to the room and get toys from the common room. Tr. 41. She stated that it was such an improvement from the previous nights, but that A.M. remained tired. Tr. 41-42. On the drive back from the hospital, Ms. Miller sat in the back of the car with A.M. Tr. 43. She testified that A.M. did not really interact with her in the car and that A.M. "sat real still," and was tired. Tr. 42.

Ms. Miller testified that A.M. experienced another tonic-clonic seizure on January 2, 2016. Tr. 44. The family went to a restaurant and while waiting to order their food, A.M. began "zoning out." Tr. 45. Her eyes rolled back in her head and she began to slip under the table and "seize." *Id.*

Ms. Miller explained that between the first seizures and the seizure in January 2016, she noticed that A.M.'s verbal skills were not progressing. Tr. 47. A.M. was experiencing balance issues and began to "space out." Tr. 45-47. Ms. Miller testified that A.M. did not sing or dance as she used to and she was described as having absence seizures frequently and more so when she had a little fever or a cough. Tr. 11-12, 47.

VI. Discussion and Finding of Facts

A. Petitioner has shown that A.M. suffered encephalopathy within the applicable timeframe.

For a Table injury resulting from the MMRV vaccination, a vaccine recipient must show that the encephalopathy occurred within five to fifteen days after vaccine administration. A.M. received her MMRV vaccination on May 27, 2015. Pet. Ex. 3 at 211, 319. She suffered her first seizure on June 3, 2015. Pet. Ex. 12 at 2; Pet. Ex. 1 at 295-98. A.M. suffered a second seizure on June 4, 2015. Pet. Ex. 1 at 218.

A.M.'s first seizure occurred six days after the MMRV vaccination, well within in the Table's applicable timeframe.

B. Petitioner has shown that A.M. suffered a seizure associated with loss of consciousness.

The medical records establish that A.M. suffered two "complex febrile seizure" on June 3, 2015 and June 4, 2015, each episode lasting less than five minutes. *See* Pet. Ex. 1 at 207, 218, 285. Complex febrile seizure includes a loss of consciousness and occurs more than once within a 24-hour period.[5] The testimony provided by both Mr. and Ms. Miller was consistent with the medical record and specifically describe that A.M. dropped to the ground, lost consciousness, her eyes rolled back in her head and she foamed at the mouth during the first episode. Tr. 14, 24, 86 & 98. The second episode was observed in the hospital leading to the diagnosis and was described as a complex febrile seizure.

Based on the medical record and the testimony, at the conclusion of the witness testimony, I concluded that A.M. suffered a seizure associated with the loss of consciousness. Tr. 118.

C. Petitioner established that A.M. experienced a significantly decreased level of consciousness, independent of seizures or medication that last for at least a 24-hour period.

The QAI provides that a "significantly decreased level of consciousness" is indicated by the presence of one or more of the following clinical signs: (i) decreased or absent response to environment; (ii) decreased or absent eye contact (does not fix gaze upon family members or other individuals); or (iii) inconsistent or absent responses to external stimuli (does not recognize familiar people or things). § 100.3(d)(4)(i)-(iii).

When respondent revised the QAI in 1995, respondent explained that the addition of the clinical signs constituting "a significantly decreased level of consciousness" was to "differentiate mere lethargy from the more serious impairment of consciousness that is the hallmark of encephalopathy (i.e., *obtundation,* stupor and coma)" to better define acute and chronic encephalopathy. 60 Fed. Reg. 7687 (emphasis added).

In analyzing the requirements of the QAI, I reviewed specific definitions for the terms of decreased levels of consciousness. In considering the testimony in this case, I looked to those specific definitions. According to the *Clinical Methods: The History, Physical and Laboratory Examinations* textbook, available online at the National Library of Medicine, a normal level of consciousness comprises either the state of wakefulness, awareness, or alertness in which most human beings function while not asleep.[6] Tr. 119. The abnormal state of consciousness is more difficult to define and characterize as evidenced by many terms applied to altered state of consciousness by various observers. *Id.* It continues, saying that nevertheless it is appropriate to define several of the terms as closely as possible. It lists six different levels of altered states of

[5] Mayo Clinic, *Febrile Seizures: Symptoms and* Causes (July 31, 2019), https://www mayoclinic.org/diseases-conditions/febrile-seizure/symptoms-causes/syc-20372522

[6] Tindall SC. Level of Consciousness. In: Walker HK, Hall WD, Hurst JW, editors. *Clinical Methods: The History, Physical, and Laboratory Examinations.* 3rd edition. Boston: Butterworths; 1990. Chapter 57. Available from: https://www.ncbi.nlm.nih.gov/books/NBK380/

consciousness beginning with the least severe, "clouding of consciousnesses" and ending with the most severe altered state as, "coma." Clouding of consciousness is a very mild form of altered mental status in which the patient has inattention and reduced wakefulness. The next level of altered consciousness is "confusional state" defined as a more profound deficit that includes disorientation, bewilderment, and difficulty following commands. The third level, lethargy, is defined as "severe drowsiness in which the patient can be aroused by moderate stimuli and then drift back to sleep." Tr. 120. Obtundation, defined as "a state similar to lethargy in which the patient has a lessened interest in the environment, slowed responses to stimulation, and tends to sleep more than normal with drowsiness in between sleep states," is fourth on the scale of altered states of consciousness. *Id.* These are followed by stupor and coma. *Id.*

The attending physician, Dr. Barkman, stated that A.M. "…*remained somewhat lethargic and even obtunded at times*….Over the following 36-hours, the child became more alert, playful, began eating and drinking and had no further fever.*"* when describing her behavior through the course of her hospital treatment. Pet. Ex. 1 at 205.

The interpretation of Dr. Barkman's notation has been the main source of contention between the parties. Ultimately, a fact hearing was necessary to provide further detail regarding A.M,'s behavior and level of consciousness in the hospital. Lay testimony may offer additional details to supplement medical records when a lay witness observes the patient more continuously than a medical doctor or witnesses a significant medical event outside the presence of medical personnel. This testimony can be particularly persuasive when it is more detailed and consistent with the medical records.

In the Rule 4(c) report, respondent cited to Dr. Barkman's note, stating, "*Though she remained lethargic*, her vital signs were stable. After 36 hours, she [A.M.] "'became more alert, playful, began eating and drinking and had no further fever.'" Resp. Rept. at 5 (emphasis added). In his Status Report in response to petitioner's memo in support of a Table injury, respondent then argued that it was unclear if Dr. Barkman was describing a postictal state immediately following her seizure or A.M.'s behavior throughout the hospital course. Resp. Status Report at 1-2. Respondent argued in the Status Report that the modifying words "somewhat" and "at times" in Dr. Barkman's report demonstrates that A.M.'s decreased level of consciousness was intermittent and not persistent in nature. Resp. Status Report at 2 (ECF No. 19).

The respondent's focus on the modifying words "somewhat" and "at-times," of Dr. Barkman's notation fails to acknowledge that the words "lethargic" and "obtunded" are describing an already decreased level of consciousness. The notation by Dr. Barkman puts A.M.'s baseline level of consciousness at "lethargic," which at times *fell to* "obtunded." I concluded that in using the words lethargic and obtunded, Dr. Barkman was intentionally using terms of art, as defined in this publication, to describe a significantly decreased level of consciousness that was consistent throughout A.M.'s hospitalization. A.M.'s level of consciousness worsened but was not above lethargic and did not improve until thirty-six hours later. Further, Ms. Miller's description of A.M.'s behavior between the first and second seizure was suggestive of a decreased level of consciousness that was sufficiently alarming she was advised by medical professionals to return A.M.to the hospital.

At no time before the end of the hospital stay did Dr. Barkman describe A.M.'s level of consciousness above lethargic. Instead, he states, "Over the following 36-hours, the child became more alert, playful and began eating and drinking and had no further fever." Pet. Ex. 1 at 205. Respondent argued that this sentence implied that A.M.'s level of consciousness did not remain significantly decreased for the required 24-hour period, but rather improved. Resp. Status Report at 2. Petitioner argued that the notation indicates that A.M.'s level of level of consciousness remained significantly decreased over thirty-six hours and only afterwards, did she show improvement. Pet. Memo at 7. Dr. Barkman's statement that A.M. became more alert over 36-hours illustrates the contrast in the different levels of consciousness he was observing in A.M. while she was in the hospital and at end of her hospitalization.

Ms. Miller was with A.M. from June 3rd through June 6th. She was at home with A.M. on June 4th, she transported A.M. to the hospital on June 4th and she stayed with A.M. throughout her hospital admission. Her testimony was credible, clear and consistent with the medical records. Ms. Miller testified that on June 4th, A.M. was not making eye contact, not talking or walking. Tr. 21-23; Pet. Ex. 1 at 211. A.M. did not eat. Tr. 21. She did not urinate. Tr. 21. A.M. was not responding to stimuli she normally would respond to, such as a lollipop. Tr. 22. Ms. Miller's description of A.M.'s behavior demonstrates that A.M. was experiencing a decreased level of consciousness leading up to her second seizure on June 4, 2015 at 7:55 pm. Pet. Ex. 1 at 220.

Ms. Miller explained that throughout the day of June 5th A.M. was not interested in playing with toys available to her and was sleeping a lot. Tr.67. A.M. remained in bed or in Ms. Miller's arms most of the day. *Id.* Ms. Miller testified that A.M. did not acknowledge her former babysitter, Ms. Rousette, or take a stuffed animal from her. Tr. 38. A.M. did not recognize or acknowledge the Barboas when they came to visit her in the hospital. *Id.* A.M. barely spoke to her parents that day and was more "nonresponsive than responsive". Tr. 34, 71.

Mr. Miller was witness to both of A.M.'s seizures. Tr. 85, 97. He visited A.M. in the hospital on June 5th. He testified that A.M. did not talk to him while he was at the hospital. Tr. 104. When Mr. Miller attempted to play with A.M. by being "goofy" with a stuffed animal, she did not respond. *Id.* Mr. Miller was at the hospital until approximately 8:30 pm on the evening of June 5th. Tr. 105. He described A.M.'s behavior as "lethargic and listless," while he was there. *Id.*

Mr. Barboa also witnessed A.M.'s behavior in the hospital. Tr. 77. He testified that he and his wife brought dinner to the Miller's on June 5th at the hospital. *Id.* He explained that A.M. was "not cohesive to what was going on around her or anything. She was just in a stare daze." *Id.* When he attempted to interact with A.M., she did not respond. *Id.*

A.M.'s behavior, as described by the witnesses, is consistent with Dr. Barkman's notation describing A.M.'s mental status while in the hospital. Further, Ms. Miller, Mr. Miller and Mr. Barboa's testimonies describing A.M.'s behavior established that A.M. met the clinical signs outlined in the QAI constituting a "significantly decreased level of consciousness," for a 24-hour period. Ms. Miller explained that A.M. was not making eye-contact with her on June 4th and

unengaged in her environment from June 4th until the morning of June 6th. All three witnesses testified that A.M. had inconsistent or absent responses to familiar people and A.M. did not fix her gaze on individuals or family members.

Based on the record as a whole, including the medical records, the testimony of A.M.'s parents' and Mr. Barboa, I found that A.M. demonstrated a significantly decreased level of consciousness for at least a 24-hour period. Tr. 120.

D. Petitioner has established that A.M. has suffered an acute encephalopathy.

Based on the record as a whole and in accordance with my fact findings above, I find that A.M.'s conditions met the criteria of an acute encephalopathy as set forth in the Vaccine Injury Table.

E. Petitioner has established that A.M. has chronic encephalopathy.

The medical records and the testimony of the witnesses establish that A.M. did not return to baseline within less than six months after she suffered her first acute encephalopathy.

Ms. Miller testified that following A.M.'s seizures in June 2015, her verbal skills decreased, and her motor skills became impaired. Tr. 47. Mr. Miller testified that A.M.'s behavior months following the seizures was significantly different. Tr. 114-15. The medical records show that A.M. was assessed with a developmental delay and "atypical febrile seizures following immunizations" in September 2015. In January 2016, A.M. was again assessed with developmental delays by Dr. Letellier. Pet. Ex. 11 at 39. Additionally, A.M.'s seizure activity continued, as she experienced two other seizures in January and July of 2016 and again in February 2017. Pet. Ex. 9 at 1; Pet. Ex. 11 at 4. Prior to the vaccination, A.M. had never suffered seizures and had been meeting developmental milestones.

Therefore, I find that A.M. experienced a change in neurologic and mental status that persisted for at least six months following the onset of acute encephalopathy. A.M. had chronic encephalopathy which persisted for over a six-month period.

VII. CONCLUSION

Petitioner has shown that A.M. suffered a Table encephalopathy following the MMRV vaccination. Accordingly, petitioner is entitled to compensation. A separate damages order will be issued.

IT IS SO ORDERED.

s/Thomas L. Gowen
Thomas L. Gowen
Special Master